4. 510(k) Summary of Safety and Effectiveness

Device Name:	BioLucent Applicator
Device Model Number:	**RTK-006** **RTK-008** **RTK-010**
Classification Name:	Remote Controlled Radionuclide Applicator System (JAQ), 21 CFR, 892.5700
Device Classification:	Class II
Predicate devices:	BioLucent Applicator (K062830, K061241) Wright Vaginal Cuff Applicator (K980601) Comfort Catheters (K032372) Shielded Rectal Applicator Set (K033371)
Manufacturer:	BioLucent, Inc. 6 Journey, Suite 325 Aliso Viejo, CA 92656
Establishment Registration Number:	2032338
Official Contact:	Dave Campbell BioLucent, Inc. 6 Journey, Suite 325 Aliso Viejo, CA 92656 Phone: (949) 349-1380 (x128

Intended Use:
The BioLucent Applicator is intended for use as an accessory to commercially available remote afterloading equipment used during brachytherapy procedures. The multiple lumens of the BioLucent Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

Device Description:
The BioLucent Applicator is an expandable cylindrical device with radially positioned catheters, which is inserted into the target volume. The BioLucent Applicator is provided sterile and is a single use device.

Technological Characteristics Summary
The BioLucent Applicator is equivalent to the predicate devices, with the same principles of operation and overall technological characteristics.

Performance Data Summary
Performance testing was conducted on the BioLucent Applicator to demonstrate the integrity, suitability and substantial equivalence of the device.

Conclusion:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the BioLucent Applicator is determined to be substantially equivalent to existing legally marketed devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2007

Mr. Dave Campbell
Director of Operations
BioLucent, Inc.
6 Journey, Suite 325
ALISO VIEJO CA 92656

Re: K070659
Trade/Device Name: BioLucent Applicator Kit
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 6, 2007
Received: March 7, 2007

Dear Mr. Campbell:

This letter corrects our substantially equivalent letter of April 4, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of the BioLucent Applicator Kit for Brachytherapy as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

The Warning must be presented within a black box, and the font should be bold and the same size as any surrounding text. The Warning should be the first item in your list of warnings.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and adiological Health

Enclosure

3. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070659

Device Name:

BioLucent Applicator Kit

Indications for Use:

The BioLucent Applicator Kit is intended for use as an accessory to commercially available remote afterloading equipment used during brachytherapy procedures. The multiple lumens of the BioLucent Applicator are intended to provide pathways from which a prescribed radiation dose is delivered to the treatment area.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070659